

**ATTACHMENT A**  
**Remarks**

Claims 1, 10-26, 30, 31 and 39-67 are pending in the present application. By this Amendment, Applicants have amended claims 24, 30 and 48. Applicants respectfully submit that the present application is in condition for allowance based on the discussion which follows.

Claims 1, 10, 24, 30, 31, 39, 40, 48 and 52 were rejected under 35 U.S.C. § 102(e) as being anticipated by Thalgott (U.S. Patent No. 6,558,424) (hereinafter "Thalgott").

Contrary to the rejection, previously presented claims 1, 10, 48 and 52 are not anticipated by Thalgott, as Thalgott fails to disclose all features of the claimed invention. Specifically with regard to claim 1, Thalgott fails to disclose an instrument for inserting into an intervertebral space, an intervertebral implant comprising a pair of arms in which each arm includes at its outer end, a recess engaging portion adapted to be inserted into a recess in the intervertebral implant. The arms are constructed to close towards each other to enter recesses in the top and bottom of the implant.

In sharp contrast to the present invention, Thalgott clearly discloses an instrument for inserting into recesses exclusively in the anterior side of an implant, not the top and bottom of an implant. Referring to Thalgott, Figures 8-10, instrument 120 includes grasping elements 122, 124 having a shape and size adapted to fit into a groove 140 formed in the anterior side 78 of the ring element 80. Thalgott, column 9, lines 27-34 and Figure 10. Therefore, Thalgott fails to disclose an instrument with upper and lower arms, which are inserted into respective recesses found in the top and bottom of the implant. Accordingly, Thalgott fails to anticipate claim 1.

With regard to the subject matter of claim 48, Thalgott fails to disclose a method for inserting into an intervertebral space an intervertebral implant having an upper part and a lower part, let alone securing an upper part and a lower part of an intervertebral implant with arms of an insertion instrument that move in a circular pattern. Nowhere does Thalgott disclose a two-part implant having an upper part and a lower part. To the contrary, Thalgott merely discloses an implant having a ramp member, such as ramp member 20, and a ring member, such as ring member 80. However, nowhere does Thalgott disclose an implant having an upper and lower part. Accordingly, Applicants respectfully request that the rejection to claims 48 and 52, as being anticipated by Thalgott under 35 U.S.C. § 102(e), be withdrawn.

With regard to claims 24 and 30, by this Amendment, Applicants have amended these claims to further recite an additional feature of the present intervertebral implant, namely that the implant has upper and lower parts which engage each other for relative movement therebetween. Accordingly, the subject matter of claims 24 and 30 are not disclosed in and thus not anticipated by Thalgott. For example, with regard to the subject matter of claim 24, as discussed above, Thalgott fails to disclose an implant or an intervertebral insertion tool for inserting an intervertebral implant having an upper part and a lower part into an intervertebral space. Therefore, since Thalgott fails to disclose an intervertebral implant having an upper part and a lower part, Thalgott fails to disclose upper and lower parts which engage with each other for relative movement therebetween.

Further, Thalgott fails to disclose an intervertebral implant having a top which, in the intervertebral space, engages one vertebrae surface, and a bottom which, in the

intervertebral space, engages the other vertebrae surface. Since the Thalgott implant fails to disclose an intervertebral implant having a bottom or lower part which engages the other vertebrae surface, Thalgott fails to in any way anticipate the claimed instrument in combination with an intervertebral implant.

With regard to claim 30, Thalgott fails to disclose an intervertebral implant having an upper part and a lower part which engage each other and thus fails to disclose a method of inserting such an intervertebral implant. Further, Thalgott fails to disclose the step of moving the forward ends of an insertion instrument, such that the ends of the arms of the insertion instrument securely hold the intervertebral implant while urging the upper and lower parts towards each other. Since Thalgott fails to disclose an upper or lower part, Thalgott fails to anticipate urging the upper part and lower part towards each other.

Based on the foregoing, Applicants respectfully request that the rejection of claims 1, 10, 24, 30, 31, 39, 40, 48 and 52, as being anticipated under 35 U.S.C. § 102(e) by Thalgott, be withdrawn.

Claims 11-23, 25, 26, 41-47, 49-51 and 53-67 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Thalgott in view of Moskovich (U.S. Patent No. 5,431,658) (hereinafter "Moskovich").

Contrary to the rejection, Thalgott, in view of Moskovich, fails to make obvious the subject matter of the aforementioned claims. Thalgott and Moskovich are directed to completely different insertion tools, each designed for a respective very specific purpose for manipulating a highly specialized and completely different implant. Moskovich is directed to a tool for a vertebrae graft insertion between two vertebrae.

Thalgott is directed to a modular fusion device which includes a ramp element which is first inserted between two vertebrae followed by insertion of a ring unit around the ramp.

There fails to be any apparent reason why one of ordinary skill in the art would have combined the insertion tool for a modular fusion device of Thalgott with the Moskvich bone graft insertion tool. In order for two references to be combined in an obviousness type rejection under 35 U.S.C. § 103(a), there must be “a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int’l. Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_\_ (2007), Slip Opinion at page 14. Although the Examiner alleges that the reason one of ordinary skill in the art would have combined Thalgott with Moskvich is “to push the implant between the vertebrae and also push the end of the lower arms out from between the vertebrae,” such a reason has no basis in the references, let alone in the art, in general.

Further, the Examiner’s statement is merely conclusionary and no facts have been alleged by the Examiner to support such an assertion. For example, nowhere in the cited prior art references is there any disclosure of a problem with how the implant of Thalgott is inserted between adjacent vertebrae. To the contrary, specifically, Figures 8A and 8B illustrate an insertion tool having handle 108 for inserting the ramp member 94 between adjacent vertebrae. An alternative insertion tool is disclosed for use in inserting the ring member around the ramp, as shown in Figures 9A and 9B. Accordingly, Thalgott fails to recognize an advantage of the present specialized tool, which includes a tool which both manipulates a completely different and specialized

implant having an upper and lower part, as well as an insertion tool having a spacer module between the upper and lower arms of the insertion tool for engaging the implant.

Further, even if, *arguendo*, one of ordinary skill in the art would combine Thalgott with Moskovich, the combined disclosure fails to enable one of ordinary skill in the art to practice the invention as claimed. In particular, the Thalgott insertion tool is specifically designed to hold a single piece implant by insertion in a groove formed in its anterior surface. The combined references fail to teach or in any way make obvious how one of ordinary skill in the art would accommodate the spacer of Moskovich and locate it between the arms of the insertion tool of Thalgott. It is only using the present disclosure that one of ordinary skill in the art would be able to fashion an insertion tool having a scissor-like action and including a spacer module between the upper and lower arms. Only using impermissible hindsight, using the present disclosure as a blueprint, would one of ordinary skill in the art know how to fashion an instrument to enable one of ordinary skill in the art to practice the invention as claimed.

Moreover, one of ordinary skill in the art would find no benefit to including the spacer element of Moskovich with the insertion tool of Thalgott, as such a spacer would serve no purpose in the insertion of the Thalgott implant. As previously discussed, a separate instrument is used for inserting the ramp element between two adjacent vertebrae. The combined teachings of Thalgott and Moskovich fail to in any way teach how the spacer of Moskovich could be used to insert any portion of the instrument of Thalgott. Therefore, there fails to be any benefit derived from combining Thalgott with the spacer of Moskovich.

With regard specifically to claim 41, the prior art, individually or in combination with one another, fails to teach or in any way make obvious a method of inserting into an intervertebral space, an intervertebral implant having an upper part and a lower part, which includes placing a spacer which is located between an upper and a lower arm of the insertion tool, partially into the space between the upper part and the lower part, to limit movement of the upper and lower parts towards each other in the vicinity of the spacer. The prior art, individually or in combination with one another, fails to teach or in any way make obvious an intervertebral implant having an upper part and a lower part, let alone a space inserted between an upper part and a lower part which limits movement of the upper and lower parts towards each other.

With regard to claim 46, the prior art, individually or in combination, fails to teach or make obvious inserting into an intervertebral space, an intervertebral implant having an upper part and a lower part, which includes locating the lower part of the implant on the lower arm of an insertion instrument, moving a spacer into a portion of the lower part, locating the upper part of the implant on the upper arm of the insertion instrument, and moving the upper and lower arms together to secure the implant with the spacer located between the upper and lower parts to limit movement of the upper and lower parts together in the vicinity of the spacer. As previously discussed, the prior art fails to teach or in any way make obvious an implant having a lower part, an upper part or a spacer moved into a portion of the lower part. Accordingly, the prior art fails to teach or in any way make obvious the subject matter of claim 46.

Further, the prior art fails to teach or in any way make obvious the subject matter of claim 47, dependent from claim 46, which further includes moving the implant

secured by the arms of the insertion tool with the spacer and placing the implant into an intervertebral space and, subsequently, removing the insertion instrument from the intervertebral space, leaving the implant in the intervertebral space.

With regard to the subject matter of claim 49, the prior art, individually or in combination, fails to teach or in any way make obvious a method for inserting an intervertebral implant into an intervertebral space, which includes positioning a spacer between upper and lower arms of the insertion tool, with a portion thereof located between the upper and lower parts of the implant to limit movement of the upper and lower parts towards each other in the vicinity of the spacer. As previously discussed, the prior art fails to teach or in any way make obvious an implant having an upper and lower part, let alone a spacer moved between the upper and lower parts to limit movement therebetween.

Similarly, with regard to claim 53, the prior art, individually or in combination, fails to teach or in any way make obvious an instrument for inserting into an intervertebral space an implant in which the instrument has upper and lower arms and a spacer between the upper and lower arms which is movable into a space between upper and lower parts of an implant.

Further, with regard to claim 58, the prior arts fails to teach or in any way make obvious an implant having upper and lower parts and a space movable relative to upper and lower arms in the instrument, which is movable into a space between upper and lower parts of the implant to limit movement of the upper and lower parts towards each other in the vicinity of the implant.

Finally, with regard to claim 63, the prior art, individually or in combination, fails to teach or in any way make obvious a method of inserting an intervertebral implant comprising an upper part and a lower part into an intervertebral space and moving a spacer in between upper and lower parts of the implant to limit movement of the upper and lower parts of an implant as claimed.

Based on the foregoing, Applicants respectfully request that the rejection to claims 11-23, 25, 26, 41-47, 49-51 and 53-67, as being obvious under 35 U.S.C. § 103(a) in view of Thalgott and Moskovich, be withdrawn.

In view of the foregoing, Applicants respectfully submit that the present application is in condition for allowance.

**END REMARKS**